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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,768	01/18/2002	Uwe Hahnann	2565/94	7106
26646	7590	11/28/2003	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			KIM, SUN U	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 11/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/052,768	HAHMANN ET AL.	
	Examiner	Art Unit	
	John Kim	1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-38 and 55-69 is/are pending in the application.
- 4a) Of the above claim(s) 55-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-38 and 59-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/441,182.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

1. Claims 55-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 7.

2. Applicants' submitted drawing corrections and replacement drawings on 9/8/03 are missing. Examiner requests these drawings to be resubmitted.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 36-38 and 59-69 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for filter module **having a plurality of connections for supplying or removing a fluid from the device and each connection** having the claimed subject matter, does not reasonably provide enablement for any filter module without a plurality of connection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Newly amended claim 36 deleted the original recitation of "having a plurality of connection for supplying or removing a fluid from the device, each of said connections". Claims are drawn for the particular connection in a filter module and not for filter module itself.

5. Claims 36-38, 59-62 and 65-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,197,848 (hereinafter referred to as Garrett et al). Garrett et al teach a closure element (42, 46) in a medical device comprising a resilient wall (42) with a resiliently deformable slit (56) and a cylindrical integral skirt (46) wherein wall and skirt are made of latex

and resilient slit prevents entry of air (see figures 1-4; col. 4, line 37 - col. 5, line 18). Lip (36), inner and outer annulus (34, 38) hold the closure element (42, 46) and thus, satisfies the means for fastening the closure element to a connecting element (see col. 4, lines 23-48). Claim 36-38, 59-60, 62, 65-66 and 68 essentially differ from the device of Garrett et al in reciting a filter module. It would have been obvious to a person of ordinary skill in the art to incorporate a closure element of Garrett et al in a common medical filter module such as a dialyzer, hemofilter and ultrafiltration filters with a plurality of connections for providing sterile connections between a tubing and the filter module. Regarding claim 61, Garrett et al discloses the claimed invention except for slit-shaped indentation in a shape of a cross or a star. It would have been an obvious matter of design choice to modify the slit of Garrett et al in a shape of cross or a star, since applicant has not disclosed that slit indentation in a shape of cross or a star solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with a slit in any shape. Regarding claim 67, Garrett et al meets the limitation except that the wall and the closure element is made of resilient, liquid and air impervious material such as latex or other similar material rather than silicone. However, because these latex or other similar materials and silicone were art-recognized equivalents at the time of the invention in a sealant material, one of ordinary skill would have found it obvious to substitute silicone as sealing closure material for latex or other similar material. Regarding claim 69, the slit (56) of Garrett et al is made of a resilient material. It would have been obvious to a person of ordinary skill in the art to modify the resilient material of slit to withstand the desired pressure difference such as a pressure difference up to about plus or minus 0.25 to allow connection between a tube and a connecting element.

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6. Claims 36-38, 60-64 and 66-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,929,235 (hereinafter referred to as Merry et al). Merry et al teach a closure element (26, 29) in a medical device comprising a first gasket (26) with a resiliently deformable Y-slit (27) and a second gasket (29) with a central opening (31) wherein gaskets are made of silicone and resilient slit prevents entry of air (see figures 1-4; col. 4, line 37 - col. 5, line 18). Spacer ring (28) and valve body (11) hold the closure element (26, 29) and thus, satisfies the means for fastening the closure element to a connecting element (see figure 1). Claim 36-38, 60, 62-63 and 66-68 essentially differ from the device of Merry et al in reciting a filter module. It would have been obvious to a person of ordinary skill in the art to incorporate a closure element of Merry et al in a common medical filter module such as a dialyzer, hemofilter and ultrafiltration filters with a plurality of connections for providing sterile connections between a tubing and the filter module. Regarding claim 61, Merry et al discloses the claimed invention except for slit-shaped indentation in a shape of a cross or a star. It would have been an obvious matter of design choice to modify the slit of Merry et al in a shape of cross or a star, since applicant has not disclosed that slit indentation in a shape of cross or a star solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with a slit in any shape. Regarding claim 64, Merry et al discloses the claimed invention except for the surface, extending around the opening in the second wall, lying in a plane substantially perpendicular to a joining direction of the closure element to the connecting tube. It would have been an obvious matter of design choice to modify the surface of Merry et al to lie in a plane substantially perpendicular to a joining direction of the closure element to the connecting tube, since applicant has not disclosed that the surface lie in this specific angle solves any stated

problem or is for any particular purpose and it appears that the invention would perform equally well with the surface lying in any angle. Regarding claim 69, Merry et al teaches a closure element (42, 46) made of resilient material. It would have been obvious to a person of ordinary skill in the art to modify the resilient material of slit to withstand the desired pressure difference such as a pressure difference up to about plus or minus 0.25 to allow connection between a tube and a connecting element.

7. Applicant's arguments with respect to claims 36-38 and 59-69 have been considered but are moot in view of the new ground(s) of rejection.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

9. This application contains claims 55-58 drawn to an invention nonelected with traverse in Paper No. 7. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response is (703) 872-9306.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.


John Kim
Primary Examiner
Art Unit 1723

J. Kim
November 22, 2003